

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended): A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil and mixtures thereof; ~~and~~

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition; and

(c) Carnallite or a salt of Carnallite.

2. (previously presented): A solid composition according to claim 1 wherein said composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to oral mucosal tissue for at least 30 minutes.

3. (previously presented): A solid composition according to claim 1 wherein said composition is in the form of a disc of 5 to 11 mm diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour.

4. (previously presented): A composition according to claim 1, wherein the herbal active agent is at least one selected from the group consisting of an anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, and an antiparasite agent.

5. (canceled).

6. (previously presented): A composition according to claim 1, wherein the herbal active agent or homeopathic active agent is at least one selected from the group consisting of Gotu Kola, Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, Elder, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, and Radix gentianae Longdancao antifungal agent.

7. (previously presented): The composition of claim 1, wherein the herbal active agent is at least one essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil,

SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. § 1.114(c)

U.S. Application No. 10/083,413

Q63391

cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil.

8. (previously presented): The composition of claim 1, wherein the herbal active agent is at least one essential oil selected from the group consisting of cinnamon oil, tea-tree oil and citronella oil.

9. (previously presented): A composition according to claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. (previously presented): A composition according to claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one of myrcene, a- pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. (previously presented): A composition according to claim 9, wherein said monoterpenes with three unsaturations is at least one citrus oil selected from the group consisting of lemon, pomelo and citron.

12. (original): A composition according to claim 6, further comprising a salt selected from the group consisting of MgBr_2 , NaCl, KCl and mixtures thereof.

13. (canceled).

14. (currently amended): A composition according to claim ~~13~~1, wherein said Carnallite or salt of Carnallite is present in an amount of about 5-50% wt/wt based on the amount of the at least one herbal active agent or homeopathic active agent.

15. (previously presented): The composition of claim 1, further comprising a non-herbal active agent selected from the group consisting of anesthetic agent, analgesics, steroidal and non-steroidal anti-inflammatory agents, antihistaminic or antiallergics, steroids, antimicrobial drugs, vitamins, enzymes, anti-allergic drugs, antipyretics, antimalarial, antiulcer drugs, peptides, DNA plasmid and antisense based therapeutic agents.

16. (previously presented): The composition of claim 15, wherein the anesthetic agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chlorprocaine, tetracaine, bupivacaine, and etidocaine.

17. (previously presented): The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

18. (currently amended): The composition of claim 4, ~~further comprising~~ wherein said Carnallite or a salt of Carnallite ~~which~~ improves the activity of the herbal active agents.

19. (previously presented): The composition of claim 4, wherein the herbal active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. (previously presented): The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1.

21. (previously presented): The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivacaine.

22. (previously presented): The composition of claim 1, wherein the solid bioadhesive carrier is selected from a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.

23. (previously presented): The composition of claim 22 wherein said polyhydric polymer comprises at least one member selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymers of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers, and mixtures thereof.

24. (currently amended): ~~A composition according to claim 22~~ A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil and mixtures thereof; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition, wherein the solid bioadhesive carrier is selected from a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof;

wherein said solid, self-bioadhesive composition is in the form of a tablet wherein said composition additionally contains one or more members selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and lubricants.

25. (previously presented): A composition according to claim 24 wherein said enhancers are selected from salts of bile acids and limonene.

26. (previously presented): A composition according to claim 22 wherein said solid bioadhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose and mixtures thereof.

Claims 27-34. (canceled).

35. (new): A composition according to claim 24 wherein said composition additionally comprises Carnallite or a salt of Carnallite.

36. (new): A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

- (a) a therapeutically effective amount of at least one homeopathic active agent, and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition.

37. (new): A composition according to claim 36 wherein said composition additionally comprises Carnallite or a salt of Carnallite.